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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,799	08/29/2003	Barry Eisenstein	50150/005003	2013
21559	7590	05/19/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			JOYNES, ROBERT M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/652,799	Applicant(s) EISENSTEIN, BARRY	
	Examiner Robert M. Joynes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-75 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 and 54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chamberland et al. (US 6114310) in combination with Rose et al. (US 6316433). Chamberland teaches that rifamycins can be used to treat *Clostridium Difficile* (Claims 15, 16 and 25). Chamberland does not expressly teach all the specific rifamycins.

Rose teaches that rifalazil is a known rifamycin that is known to treat bacterial infections (col. 5, lines 28-49; Col. 6, lines 11-43).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to treat *Clostridium Difficile* with rifalazil, a known rifamycin. The primary reference teaches that rifamycins treat *Clostridium Difficile* and the secondary

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reference teaches that rifalazil is a known rifamycin. Therefore, it would have been obvious to use rifalazil to treat *Clostridium Difficile*.

The references do not expressly teach all of the claimed treatment regimes. However, absent a clear showing of criticality, the determination of particular ranges and administration regimes is within the skill of the ordinary worker as part of the process of normal optimization. The courts have held the "concentration limitations are obvious absent a showing of criticality." Azko v. E.E. Pont de Nemours, 1 USPQ 2d 1704 (Fed. Cir. 1987).

One of ordinary skill in the art would have been motivated to do this because rifalazil is stable and potent (See Rose).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 13,34, 35, 37-53, 59, 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chamberland et al. (US 6114310) in combination with Rose et al. (US 6316433) in further combination with Bostwick et al. (US 5773000). The teachings of Chamberland and Rose are discussed above. Neither reference expressly teaches the inclusion of additional antibiotics/antibacterial/antimicrobials.

Bostwick teaches that vancomycin and metronidazole are also known to treat *Clostridium Difficile* in combination with other active agents (Col. 2, line 63 – Col. 3, line 3; Claim 6).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine rifalazil, a known rifamycin, with vancomycin or

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metronidazole to treat *Clostridium difficile*. As stated in *In Re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art.

The references do not expressly teach all of the claimed treatment regimes. However, absent a clear showing of criticality, the determination of particular ranges and administration regimes is within the skill of the ordinary worker as part of the process of normal optimization. The courts have held the "concentration limitations are obvious absent a showing of criticality." Azko v. E.E. Pont de Nemours, 1 USPQ 2d 1704 (Fed. Cir. 1987).

One of ordinary skill in the art would have been motivated to do this to better treat the bacterial infection by combining the active agents of rifalazil and vancomycin or metronidazole.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 12, 14-33, 36 and 60-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chamberland et al. (US 6114310) in combination with Rose et al. (US 6316433) in further combination with the admission of applicant in their Specification. The teachings of Chamberland and Rose are discussed above. Neither reference expressly teaches the inclusion of every antibiotic/antibacterial recited in the

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instant claims. Chamberland does list many of the recited antibiotics but not all as being known. Applicants admit in their own specification that these recited drugs are known and have known dosages for each (See Pages 12-13 of the instant Specification).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine rifalazil, a known rifamycin, with any listed antibiotic/antibacterial for treating *Clostridium difficile*. As stated in *In Re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art.

The references do not expressly teach all of the claimed treatment regimes. However, absent a clear showing of criticality, the determination of particular ranges and administration regimes is within the skill of the ordinary worker as part of the process of normal optimization. The courts have held the "concentration limitations are obvious absent a showing of criticality." Azko v. E.E. Pont de Nemours, 1 USPQ 2d 1704 (Fed. Cir. 1987).

One of ordinary skill in the art would have been motivated to do this to better treat the bacterial infection by combining the active agents of rifalazil and vancomycin or metronidazole.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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